

As Filed On  
Oct. 23, 2003

PTO/SB/05 (08-03)

Approved for use through 07/31/2006. OMB 0651-0032  
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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# UTILITY PATENT APPLICATION TRANSMITTAL

(only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.

2099.0010001/JAG/LAV

First Inventor

SILANES

Title

Pharmaceutical Composition of F(ab')<sub>2</sub>  
Antibody Fragments...

Express Mail Label No.

## APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

## ADDRESS TO:

Mail Stop Patent Application  
Commissioner for Patents  
P.O. Box 1450  
Alexandria VA 22313-1450

1. ☒ Fee Transmittal Form (e.g., PTO/SB/17)  
(Submit an original, and a duplicate for fee processing)

2. ☒ Applicant claims small entity status.  
See 37 CFR 1.27.

3. ☒ Specification [Total Pages 32]  
(preferred arrangement set forth below)  
- Descriptive title of the Invention  
- Cross Reference to Related Applications  
- Statement Regarding Fed sponsored R & D  
- Reference to sequence listing, a table,  
or a computer program listing appendix  
- Background of the Invention  
- Brief Summary of the Invention  
- Brief Description of the Drawings (if filed)  
- Detailed Description  
- Claim(s)  
- Abstract of the Disclosure

4. ☒ Drawing(s) (35 U.S.C. 113) [Total Sheets 8]

5. Oath or Declaration [Total Pages 2]  
a. ☐ Newly executed (original or copy)  
b. ☒ Copy from a prior application (37 CFR 1.63(d))  
(for continuation/divisional with Box 18 completed)

i. ☐ DELETION OF INVENTOR(S)  
Signed statement attached deleting inventor(s)  
named in the prior application, see 37 CFR  
1.63(d)(2) and 1.33(b).

6. ☒ Application Data Sheet. See 37 CFR 1.76.

7. ☐ CD-ROM or CD-R in duplicate, large table or Computer Program  
(Appendix)

8. Nucleotide and/or Amino Acid Sequence Submission  
(if applicable, all necessary)

a. ☐ Computer Readable Form (CRF)

b. Specification Sequence Listing on:

i. ☐ CD-ROM or CD-R (2 copies); or

ii. ☐ paper

c. ☐ Statements verifying identity of above copies

## ACCOMPANYING APPLICATION PARTS

9. ☐ Assignment Papers (cover sheet & document(s))

10. ☐ 37 CFR 3.73(b) Statement ☐ Power of Attorney  
(when there is an assignee)

11. ☐ English Translation Document (if applicable)

12. ☐ Information Disclosure Statement (IDS)/PTO-1449 ☐ Copies of IDS  
Citations

13. ☒ Preliminary Amendment

14. ☒ Return Receipt Postcard (MPEP 503)  
(Should be specifically itemized)

15. ☐ Certified Copy of Priority Document(s)  
(if foreign priority is claimed)

16. ☐ Nonpublication Request under 35 U.S.C. 122 (b)(2)(B)(i). Applicant must attach  
form PTO/SB/35 or its equivalent.

17. ☒ Other: Authorization under 37 C.F.R. § 1.136(a)(3)

18. If a CONTINUING APPLICATION, check appropriate box, and supply the requisite information below and in a preliminary amendment,  
or in an Application Data Sheet under 37 CFR 1.76:

☐ Continuation ☒ Divisional ☐ Continuation-in-Part (CIP) of prior application No: 09/798,076  
Prior application information: Examiner Saunders, David A. Art Unit: 1644

For CONTINUATION OR DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 5b, is  
considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only  
be relied upon when a portion has been inadvertently omitted from the submitted application parts.

## 19. CORRESPONDENCE ADDRESS

☒ Customer Number 26111

or ☐ Correspondence address below

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STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Attorneys at Law

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COUNTRY

TELEPHONE

FAX

NAME (Print/Type)

Jorge A. Goldstein

Registration No. (Attorney/Agent)

29,021

SIGNATURE

Date

10/22/03

This collection of information is required by 37 CFR 1.53(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you are required to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop Patent Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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As Filed On  
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# FEE TRANSMITTAL for FY 2003

Effective 01/01/2003. Patent fees are subject to annual revision.

☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$)**1032.00**

Complete if Known

Application Number

To be assigned

Filing Date

HEREWITH

First Named Inventor

SILANES

Examiner Name

To be assigned

Art Unit

To be assigned

Attorney Docket No.

2099.0010001/JAG/LAV

## METHOD OF PAYMENT (check all that apply)

☐ Check ☒ Credit card ☐ Money Order ☒ Other\*\* ☐ None  
\*\* Charge any deficiencies or credit any overpayments in the fees or fee calculations of Parts 1, 2 and 3 below to Deposit Account No. 19-0036.

☐ Deposit Account

Deposit Account Number 19-0036

Deposit Account Name: Sterne, Kessler, Goldstein & Fox P.L.L.C.

The Commissioner is authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☐ Credit any over payments

☐ Charge any additional fee(s) during the pendency of this application

☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

## FEE CALCULATION

### 1. BASIC FILING FEE

Large Entity Small Entity

| Fee Code          | Fee (\$) | Fee Code | Fee (\$) | Fee Description        | Fee Paid |
|-------------------|----------|----------|----------|------------------------|----------|
| 1001              | 770      | 2001     | 385      | Utility filing fee     | 385.00   |
| 1002              | 340      | 2002     | 170      | Design filing fee      |          |
| 1003              | 530      | 2003     | 265      | Plant filing fee       |          |
| 1004              | 770      | 2004     | 385      | Reissue filing fee     |          |
| 1105              | 160      | 2005     | 80       | Provisional filing fee |          |
| SUBTOTAL (1) (\$) |          |          |          |                        | 385.00   |

### 2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

| Extra                       | Fee from below | Fee Paid |
|-----------------------------|----------------|----------|
| Total Claims 71 - 20** = 51 | X 9.00 =       | 459.00   |
| Indep. Claims 4 - 3** = 1   | X 43.00 =      | 43.00    |
| Multiple Dependent          | 145.00 =       | 145.00   |

| Large Entity        |          | Small Entity |          | <u>Fee Description</u>                                       |
|---------------------|----------|--------------|----------|--|
| Fee Code            | Fee (\$) | Fee Code     | Fee (\$) |  |
| 1202                | 18       | 2202         | 9        | Claims in excess of 20                                       |
| 1201                | 86       | 2201         | 43       | Independent claims in excess of 3                            |
| 1203                | 290      | 2203         | 145      | Multiple dependent claim, if not paid                        |
| 1204                | 86       | 2204         | 43       | **Reissue independent claims<br>over original patent         |
| 1205                | 18       | 2205         | 9        | **Reissue claims in excess of 20<br>and over original patent |
| <b>SUBTOTAL (2)</b> |          |              |          | <b>(\$)</b> 647.00   |

\*\*or number previously paid, if greater; For Reissue, see above

## FEE CALCULATION (continued)

### 3. ADDITIONAL FEES

Large Entity Small Entity

| Fee Code | Fee (\$) | Fee Code | Fee (\$) | Fee Description  | Fee Paid |
|----------|----------|----------|----------|--|----------|
| 1051     | 130      | 2051     | 65       | Surcharge - late filing fee or oath  |          |
| 1502     | 50       | 2052     | 25       | Surcharge-late provisional filing fee or cover sheet                       |          |
| 1053     | 130      | 1053     | 130      | Non-English specification  |          |
| 1812     | 2,520    | 1812     | 2,520    | For filing a request for ex parte reexamination                            |          |
| 1804     | 920*     | 1804     | 920*     | Requesting publication of SIR prior to Examiner action                     |          |
| 1805     | 1,840*   | 1805     | 1,840*   | Requesting publication of SIR after Examiner action                        |          |
| 1251     | 110      | 2251     | 55       | Extension for reply within first month                                     |          |
| 1252     | 420      | 2252     | 210      | Extension for reply within second month                                    |          |
| 1253     | 950      | 2253     | 475      | Extension for reply within third month                                     |          |
| 1254     | 1,480    | 2254     | 740      | Extension for reply within fourth month                                    |          |
| 1255     | 2,010    | 2255     | 1,005    | Extension for reply within fifth month                                     |          |
| 1401     | 330      | 2401     | 165      | Notice of Appeal   |          |
| 1402     | 330      | 2402     | 165      | Filing a brief in support of an appeal                                     |          |
| 1403     | 290      | 2403     | 145      | Request for oral hearing   |          |
| 1451     | 1,510    | 1451     | 1,510    | Petition to institute a public use proceeding                              |          |
| 1452     | 110      | 2452     | 55       | Petition to revive - unavoidable   |          |
| 1453     | 1,330    | 2453     | 665      | Petition to revive - unintentional   |          |
| 1501     | 1,330    | 2501     | 665      | Utility issue fee (or reissue)   |          |
| 1502     | 480      | 2502     | 240      | Design issue fee   |          |
| 1503     | 640      | 2503     | 320      | Plant issue fee  |          |
| 1460     | 130      | 1460     | 130      | Petitions to the Commissioner  |          |
| 1807     | 50       | 1807     | 50       | Processing fee under 37 CFR 1.17(q)  |          |
| 1806     | 180      | 1806     | 180      | Submission of Information Disclosure Stmt                                  |          |
| 8021     | 40       | 8021     | 40       | Recording each patent assignment per property (times number of properties) |          |
| 1809     | 770      | 2809     | 385      | Filing a submission after final rejection (37 CFR 1.129(a))                |          |
| 1810     | 770      | 2810     | 385      | For each additional invention to be examined (37 CFR 1.129(b))             |          |
| 1801     | 770      | 2801     | 385      | Request for Continued Examination (RCE)                                    |          |
| 1802     | 900      | 1802     | 900      | Request for expedited examination of a design application                  |          |

Other fee (specify) \_\_\_\_\_

\* Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$)

## SUBMITTED BY

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Jorge A. Goldstein

Registration No.  
(Attorney/Agent)

29,021

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202-371-2600

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10/22/03

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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\*Admitted only in Maryland  
\*Admitted only in Virginia  
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Federal Agencies

October 22, 2003

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*As Filed On*  
*Oct. 23, 2003*

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

**Mail Stop Patent Application**

Re: U.S. Non-Provisional Divisional Utility Patent Application under  
37 C.F.R. § 1.53(b)  
Appl. No.: *To be assigned*; Filed: HERewith (October 23, 2003)  
(Based on U.S. Appl. No. 09/798,076; Filed: March 5, 2001)  
For: **Pharmaceutical Composition of F(ab')<sub>2</sub> Antibody Fragments and a  
Process for the Preparation Thereof**  
Inventors: Silanes *et al.*  
Our Ref: 2099.0010001/JAG/LAV

Sir:

The following documents are forwarded herewith for appropriate action by the U.S.  
Patent and Trademark Office:

1. USPTO Utility Patent Application Transmittal Form PTO/SB/05;
2. PTO Fee Transmittal (PTO/SB/17);
3. Form PTO-2038 Credit Card Payment Form in the amount of \$1032.00 to cover the appropriate fees for a small entity;
4. 37 C.F.R. § 1.136(a)(3) Authorization to Treat a Reply As Incorporating An Extension of Time;
5. Preliminary Amendment Under 37 C.F.R. § 1.115;
6. U.S. Divisional Utility Patent Application entitled:

**Pharmaceutical Composition of F(ab')<sub>2</sub> Antibody Fragments and a Process  
for the Preparation Thereof**

Commissioner for Patents  
October 22, 2003  
Page 2

and naming as inventors:

Juan López de Silanes  
Rita G. Mancilla-Nava  
Jorge F. Paniagua-Solis

the application comprising:


- a. an Application Data Sheet (37 C.F.R. § 1.76);
  - b. specification containing a total of 32 pages:
    - i. 25 pages of description prior to the claims;
    - ii. 6 pages of claims (43 claims);
    - iii. a one (1) page abstract;
  - c. 8 sheets of drawings: (Figures 1-8);
  - d. A copy of the executed Declaration, as filed in parent U.S. Appl. No. 09/798,076; and
7. Two (2) return postcards.

Correspondence should be sent to Customer Number 26111.

It is respectfully requested that, of the two attached postcards, one be stamped with the filing date of these documents and returned to our courier, and the other, prepaid postcard, be stamped with the filing date and unofficial application number and returned as soon as possible.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

  
Jorge A. Goldstein  
Attorney for Applicants  
Registration No. 29,021

JAG/LAV/nef  
Enclosures

SKGF Rec. 2/12/02 dcw; 9/5/02 mac; 6/24/03 svb

::ODMA\MHODMA\SKGF\_DC1;189554;1

Sterne, Kessler, Goldstein & Fox P.L.L.C. : 1100 New York Avenue, NW : Washington, DC 20005 : 202.371.2600 f 202.371.2540 : [www.skgf.com](http://www.skgf.com)



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



In re application of: Silanes *et al.*

[Divisional of U.S. Appl. No. 09/798,076;  
Filed: March 5, 2001]

Appl. No.: *To be assigned*

Filed: HERewith

For: **Pharmaceutical Composition of  
F(ab')<sub>2</sub> Antibody Fragments and a  
Process for the Preparation  
Thereof**

Confirmation No.: *To be assigned*

Art Unit: 1644

Examiner: *To be assigned*

Atty. Docket: 2099.0010001/JAG/LAV

**Authorization To Treat A Reply As Incorporating An Extension Of  
Time Under 37 C.F.R. § 1.136(a)(3)**

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

The U.S. Patent and Trademark Office is hereby authorized to treat any concurrent or future reply that requires a petition for an extension of time under this paragraph for its timely submission, as incorporating a petition for extension of time for the appropriate length of time. The U.S. Patent and Trademark Office is hereby authorized to charge all required extension of time fees to our Deposit Account No. 19-0036, if such fees are not otherwise provided for in such reply.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Jorge A. Goldstein  
Attorney for Applicants  
Registration No. 29,021

As Filed On  
Oct. 23, 2003

Date: 10/27/03

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::ODMA\MHODMA\SKGF\_DC1;189653;1

SKGF 1/25/02 mac; 4/18/03 svb